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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,033	CHAN ET AL.	
	Examiner	Art Unit	
	Vinod Kumar	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *22-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 December 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-21 in the reply filed on November 30, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-40 are pending.

Claims 22-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Accordingly, claims 1-21 are examined on merits in the present Office action. This restriction is made FINAL.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The disclosure is objected to because of the following informalities:

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1)

and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Page 48, lines 7-14 of the specification contain nucleotide sequences which must be referred to by their sequence identifiers as required by 37 CFR 1.821.

Description of drawings do not have SEQ ID listed with the sequences. For example, sequences in Figures 1, and 18 must be referred to by their sequence identifiers, as required by 37 CFR 1.821.

If the sequences appearing in the specification do not have sequence ID numbers assigned to them, then an amendment to the sequence listing will be required as well. There must not be any new matter submitted, therefore it is important to be careful to include only the sequences that are already disclosed in the current specification. Failure to correct the deficiency will be held a non-responsive to this Office action.

3. The specification at page 15, line 15 has misspelled "alleloe".

Appropriate action is requested.

Drawings

The drawings are objected to because of the following informalities:

4. Drawings are objected to because they fail to comply with 37CFR 1.83.

Figures 1-2, and 20-23 fail to comply with 37 CFR 1.84(g) because these figures are framed. Frames must be deleted to comply with 37 CFR 1.84(g).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Appropriate corrections are requested.

Claim Objections

5. Claims 1-4, 6-12, and 16-21 are objected to because of the following informalities:

Claims 1, 4, 6, 8, 10, 16, 17, and 18 are objected to for failing to comply with 37 CFR 1.821. The claims recite "the transcription factor Hahb-4". According to the specification (see page 10, brief description of the drawings for Figure 1) there is only

one Hahb-4 protein which is encoded by SEQ ID NO: 1 (genomic DNA) or SEQ ID NO: 2 (cDNA) and isolated from sunflower (*Helianthus annuus*). Thus, "Hahb-4" should be referred to by its sequence identification number to comply with 37 CFR 1.821.

Claims 2 and 3 recite "molecules" after "nucleic acid" in line 2, which should be singular to grammatically correspond to "molecule" which is singular in the independent claim 1.

Claim 4 is objected for reciting "wherein the molecule binds". It is not the nucleic acid molecule which binds to "5 -CAA(A/T)ATTG- 3' DNA sequence". It is the transcription factor protein which binds to a DNA. An appropriate correction is suggested.

Claim 6 is objected for lacking article before "plant" in line 4. It is suggested to insert --a-- before "plant".

Claim 7 is objected for having improper article before "nucleic acid" in line 2. It is suggested to change "the" to --a--.

Claim 8 is objected for lacking article before "plant" in line 6. It is suggested to insert --a-- before "plant".

Claim 8 is objected for reciting "vector" before "drives" in line 1. It is the promoter that drives the expression of a nucleic acid sequence. It is suggested to change "vector" to --promoter--.

Claim 8 is objected for having an improper article before "functionally" in line 4. It is suggested to change "a" to --the-- or --said--.

In claim 9, line 4, it is suggested to change "such" to --said--.

Claims 7 (line 3), 10 (line 3), 12 (line 2), 17 (line 3), 18 (line 3), 19 (line 2) and 21 (line 5) are objected for reciting "comprising". This is improper Markush claim construction. It is suggested to change "comprising" to --consisting of--. See MPEP 803.02 [R-5].

In claim 11, line 4, it is suggested to change "such" to --said transgenic--.

Claim 16 is objected for lacking article before "plant" in lines 4-5. It is suggested to insert --the-- before "plant".

Claim 20 is objected for having improper article before "plant" in line 2. It is suggested to change "the" to --a--.

Claim 21 is objected for having improper article before "nucleic acid" in line 4. It is suggested to change "the" to --a--.

Claim 21 recites "cells or cell cultures" in line 7, which should be singular to grammatically correspond to "cell or cell culture" which is singular in line 3 of the claim.

Claim 21 recites "plants" in line 8, which should be singular to grammatically correspond to "plant" which is singular in line 2 of the claim.

Appropriate action is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite

for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "the transcription factor Hahb-4" in line 2 because there is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule having a nucleic acid sequence (including SEQ ID NO: 1 or SEQ ID NO: 2) which encodes the transcription factor of Hahb-4, a transformed host cell, an environmental stress tolerant transgenic plant cell or plant, or a method of producing a water stress tolerant transgenic plant comprising said nucleic acid molecule, does not reasonably provide enablement for (a) a nucleic acid sequence encoding a functionally active fragment or variant of transcription factor Hahb-4, and (b) a nucleic acid sequence having a fragment of SEQ ID NO: 1 or SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to an isolated nucleic acid molecule encoding a functionally active fragment or variant of the transcription factor Hahb-4, and wherein the nucleic acid molecule is having the nucleic acid sequence which is a fragment of SEQ ID NO: 1 or SEQ ID NO: 2, or wherein said functionally active fragment or variant is capable of binding to a dehydration transcription regulating region of a plant species, a vector comprising a nucleic acid molecule encoding a functionally active fragment or variant of said transcription factor Hahb-4, a host cell, plant cell, plant, or plant seed transformed with said nucleic acid molecule, or wherein said transgenic plant exhibits tolerance to an environmental stress or wherein said environmental stress is drought, salinity, osmotic or cold, or a method of producing a water stress tolerant transgenic plant comprising said nucleic acid molecule.

Claims 1, 3, 7, 10, 17, 18, and 21 are directed to a fragment of SEQ ID NO: 1 or SEQ ID NO: 2. It is also important to note that Office is interpreting the recitation

"fragments thereof" in claims 7, 10, 17-18, and 21 as fragments of SEQ ID NO: 1 or SEQ ID NO: 2.

Claims 1, 4, 6, 8, 10, 16, 17, and 18 are directed to a nucleic acid sequence encoding a functionally active fragment or variant of transcription factor Hahb-4.

It must be noted that SEQ ID NO: 1 (genomic sequence) or SEQ ID NO: 2 (cDNA sequence) encode the transcription factor Hahb-4 (see specification, page 10, brief description of the drawings for Figure 1).

The instant specification, however, only provides guidance for how to make and use a nucleotide sequence (SEQ ID NO: 1 or SEQ ID NO: 2) encoding transcription factor Hahb-4, in a method of producing a transgenic plant (*Arabidopsis*) having increased tolerance to water stress (drought). See pages 33-44, examples 1-3.

The instant specification fails to provide guidance on how to make a fragment of SEQ ID NO: 1 or SEQ ID NO: 2 encoding a protein having the functional activity (e.g. drought tolerance) of Hahb-4 protein.

The instant specification fails to provide guidance on how to make a nucleic acid sequence encoding a functionally active fragment or variant of transcription factor Hahb-4 having the functional activity (e.g. drought tolerance) of Hahb-4 protein.

The specification, page 4, lines 1-10, says:

> A nucleic acid molecule encoding a functionally active fragment or variant of Hahb-4 protein, wherein the molecule is capable of binding to a 5' -CAAT(A/T)ATTG- 3' DNA sequence or to a dehydration transcription regulating region of plant species.

The specification, page 19, lines 16-27, says:

> The presence of functional DNA binding proteins in sunflower nuclei was analyzed by electrophoretic mobility shift assays using a synthetic double-stranded oligonucleotide

comprising the sequence 5'-CAAT(A/T)ATTG-3', bound *in vitro* by Hahb-4 expressed in bacteria.

The specification does not provide guidance in the specification with respect to making fragments of SEQ ID NO: 1 or SEQ ID NO: 2 having the functional activity of the transcription factor Hahb-4.

The specification does not provide guidance in the specification with respect to making nucleic acid sequences encoding functional fragment(s) or variant(s) of Hahb-4 protein which exhibit the functional activity of the transcription factor Hahb-4.

The specification does not provide guidance in the specification with respect to using said fragments of SEQ ID NO: 1, or SEQ ID NO: 2 in providing environmental stress tolerance to a host cell.

The specification does not provide guidance in the specification with respect to using said functionally active fragment(s) or variant(s) of Hahb-4 protein in providing environmental stress tolerance to a host cell.

The specification does not provide guidance on how to use a transgenic plant cell or plant comprising fragments of SEQ ID NO: 1 or SEQ ID NO: 2.

The specification does not provide guidance on how to use transgenic plant cell or plant comprising a nucleic acid sequence encoding a variant or functionally active fragment of transcription factor Hahb-4.

Thus, from the guidance in the specification, it would appear that any fragment or variant of Hahb-4 protein, including those with DNA (5'-CAAT(A/T)ATTG-3') binding activity should impart an environmental stress (e.g. drought) tolerance in a plant overexpressing said fragment or variant of Hahb-4 protein.

It is also important to note that a fragment of Hahb-4 protein would encompass unspecified size deletions in the amino acid sequence of Hahb-4 protein.

It is also important to note that a variant of Hahb-4 protein would encompass unspecified deletions, additions, substitutions and/or insertions in the amino acid sequence of Hahb-4 protein.

Making amino acid changes in Hahb-4 protein is unpredictable. While it is known that many amino acid substitutions, additions or deletions are generally possible in any given protein the positions within the protein's sequence where such amino acid changes can be made with a reasonable expectation of success (without altering protein function) are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These regions can tolerate only relatively conservative substitutions or no substitutions (see for example, Wells, Biochemistry 29:8509-8517, 1990, see pages 8511-8512, tables 1-2; Ngo et al., pp. 492-495,1994, see page 491, 1st paragraph).

Also see, Guo et al. (PNAS, 101: 9205-9210, 2004, see page 9205, abstract; page 9206, table 1; page 9208, figure 1) who teach that there is a probability factor of 34% that a random amino acid replacement in a given protein will lead to its functional inactivation. In the instant case, such a probability factor will be much higher as the claims encompass unspecified changes in the amino acid sequence of Hahb-4 protein.

Also see, Keskin et al. (Protein Science, 13:1043-1055, 2004, see page 1043, abstract) who teach that proteins with similar structure may have different functions.

Furthermore, Thornton et al. (Nature structural Biology, structural genomics supplement, November 2000, page 992, 2nd paragraph bridging columns 1 and 2) teach that structural data may carry information about the biochemical function of the protein. Its biological role in the cell or organism is much more complex and actual experimentation is needed to elucidate actual biological function under *in vivo* conditions.

The state of art teaches that plant transcription factors (TFs) consist of at least two discrete domains, a DNA binding domain and an activation or repression domain that operates together to modulate the rate of transcriptional initiation from target gene promoters. See for example, Heim et al. (Mol. Biol. Evol., 20(5):735-747, 2003; see pg 744, left column) who teach that DNA binding activity of a plant TF is regulated by a complex non-covalent interaction(s) with other transcription factor(s), which are themselves regulated by a variety of cellular responses.

This implies that fragment(s) of a plant transcription factor having only DNA binding activity (*in vitro* conditions) would be insufficient to regulate a target gene

expression in a transgenic plant overexpressing said fragment(s). For example, in the instant case, it would be highly unpredictable that a fragment of Hahb-4 protein having DNA (5' -CAAT(A/T)ATTG-3') binding activity alone would be sufficient for producing an environmental stress tolerance response when overexpressed in a plant.

The specification fails to provide guidance on domains other than the DNA binding domain of Hbhb-4 that are also required for obtaining an environmental stress tolerance response in a transgenic plant. The specification fails to provide guidance on functional fragments or variants having said non-DNA binding domains which interact with other transcription factor(s) to produce said environmental stress tolerance response in the plant.

Thus, making and analyzing proteins with a large number of amino acid changes that also have the property of providing an environmental stress tolerance through the binding with a dehydration transcription regulating region of an endogenous plant promoter would require undue experimentation. The specification does not teach how to use these sequences (functionally active fragments or variants of Hahb-4) or plants comprising them.

Additionally, claim 10 is directed to a transgenic plant having a nucleic acid molecule comprising SEQ ID NO: 1 or SEQ ID NO: 2, and claim 17 is directed to a transformed seed having a nucleic acid molecule comprising SEQ ID NO: 1 or SEQ ID NO: 2. However, these nucleic acids comprise no promoter. The specification does not teach how to use such a plant if the nucleic acid is not expressed.

Additionally, claim 16 is directed to a water stress tolerant transgenic plant comprising a nucleic acid sequence encoding Hahb-4 protein. Claim 21 is directed to a method of producing a water stress tolerant transgenic plant comprising a nucleic acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2. The claims do not mention expressing a nucleic acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2 encoding Hahb-4 protein to increase tolerance to an environmental stress. The specification does not teach how to increase abiotic stress tolerance a transgenic plant without expressing a nucleic acid sequence of SEQ ID NOs : 1 or 2, or without expressing a nucleotide sequence encoding the protein of Hahb-4 protein.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids encoding a fragment, functionally active fragment or variant of Hahb-4 protein for the functional activity (environmental stress tolerance). See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

As the specification does not describe the transformation of any plant with (i) a fragment of SEQ ID NO: 1 or SEQ ID NO: 2, or (ii) a nucleic acid sequence encoding a functionally active fragment or variant of Hahb-4 protein, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those with increased environmental stress tolerance property when expressed in a transgenic

plant, if such plants are even obtainable.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would have been required by one skilled in the art to make and use the claimed invention commensurate in scope with the teachings of the specification.

8. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

The claims are broadly drawn to an isolated nucleic acid molecule encoding a functionally active fragment or variant of the transcription factor Hahb-4, and wherein the nucleic acid molecule is having the nucleic acid sequence which is a fragment of SEQ ID NO: 1 or SEQ ID NO: 2, or wherein said functionally active fragment or variant is capable of binding to a dehydration transcription regulating region of a plant species, a vector comprising a nucleic acid molecule encoding a functionally active fragment or variant of said transcription factor Hahb-4, a host cell, plant cell, plant, or plant seed transformed with said nucleic acid molecule, or wherein said transgenic plant exhibits tolerance to an environmental stress or wherein said environmental stress is drought,

salinity, osmotic or cold, or a method of producing a water stress tolerant transgenic plant comprising said nucleic acid molecule.

The essential feature of the claims 1, 4, 6, 8, 10, 16, 17, and 18 is a nucleic acid sequence encoding a functionally active fragment or variant of transcription factor Hahb-4. The essential feature of claims 1, 3, 7, 10, 17, 18, and 21 is also a fragment of SEQ ID NO: 1 or SEQ ID NO: 2. It is also important to note that Office is interpreting the recitation "fragments thereof" in claims 7, 10, 17-18, and 21 as fragments of SEQ ID NO: 1 or SEQ ID NO: 2.

The specification describes the structure of a nucleotide sequence (SEQ ID NO: 1 or SEQ ID NO: 2) encoding the transcription factor Hahb-4. The specification also describes the function for Hahb-4 protein by overexpressing SEQ ID NO: 2 in a plant to produce water stress tolerant transgenic plant. See pages 33-44, examples 1-3. It may be noted that SEQ ID NO: 1 (genomic DNA), and SEQ ID NO: 2 (cDNA) encode Hahb-4 transcription factor protein.

The specification describes the structure for SEQ ID NO: 1 and SEQ ID NO: 2, and thus structure of fragment(s) derived from SEQ ID NO: 1 and SEQ ID NO: 2 are also described. However, the specification does not describe the function for said fragment(s). The specification fails to describe the function of environmental stress tolerance for said fragment(s).

The specification describes the structure for transcription factor Hahb-4, and thus structure of fragment(s) derived from said Hahb-4 protein is also described. However,

the specification does not describe the function for said fragments. The specification also fails to describe the function of environmental stress tolerance for said fragment(s).

The specification does not describe the structure of Hahb-4 variant(s), and thus their function is unknown.

There is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of functional (environmental stress tolerance) activity of the Hahb-4 protein. Thus, Applicant's broadly claimed genus encompasses structures whose function is unknown.

The only species described in the specification is SEQ ID NO: 1 or SEQ ID NO: 2, which encode the Hahb-4 protein.

Structures which are variant(s) of Hahb-4 protein are not described, and thus their function is unknown.

Structures which are fragment(s) of SEQ ID NOs: 1, 2 or Hahb-4 protein and having the function of increasing environmental stress tolerance when expressed in a plant are not described.

One of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NOs: 1 and 2, and their encoded protein of Hahb-4 are insufficient to describe the claimed genus.

Hence, Applicant has not, in fact, described the following: (a) functional fragments or variants of Hahb-4 protein having environmental stress tolerance property, and (b) fragments of SEQ ID NOs: 1 or 2 having environmental stress tolerance function, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Gago et al. (Plant, Cell and Environment, 25:633-640, Published May 1, 2002).

The claims are broadly drawn to an isolated nucleic acid molecule encoding the transcription factor Hahb-4, a functionally active fragment or variant thereof, having the nucleic acid sequence of SEQ ID NO: 1 or a fragment thereof, or wherein the nucleic acid molecule is a messenger RNA molecule, or wherein the nucleic acid molecule is a cDNA, having the nucleic acid sequence of SEQ ID NO: 2 or a fragment thereof, or wherein the transcription factor Hahb-4 binds to 5' -CAAT(A/T)ATG- 3' DNA sequence, or wherein the nucleic acid molecule is derived from *Helianthus annuus*, or wherein the transcription factor Hahb-4 or a functionally active fragment or variant thereof is capable of binding to a dehydration transcription regulating region of plant species, or a vector comprising a promoter operably linked to the nucleic acid sequence of SEQ ID NO: 1, SEQ ID NO: 2 or fragments thereof, or wherein the vector drives the expression of the transcription factor Hahb-4 or a functionally active fragment or variant thereof, wherein said transcription factor Hahb-4 or a functionally active fragment or variant thereof is capable of binding to a dehydration transcription regulating region of plant species.

Gago et al. disclose a nucleic acid molecule isolated from *Helianthus annuus,* comprising a nucleotide sequence encoding a homeodomain-leucine zipper transcription factor Hahb-4. The reference also discloses that said nucleic acid molecule is a RNA molecule, genomic DNA molecule or cDNA molecule. The genomic version of the nucleotide sequence disclosed in the reference has 100% sequence identity to instant SEQ ID NO: 1, and the cDNA version of the sequence disclosed in the reference has 100% sequence identity to instant SEQ ID NO: 2. The reference also discloses the protein sequence of Hahb-4 protein which has 100% sequence identity to

the protein (Hahb-4) encoded by instant SEQ ID NO: 1 or SEQ ID NO: 2. The reference further discloses that said Hahb-4 protein binds to a 5' -CAAT(A/T)ATG- 3' DNA sequence. The reference also discloses that the Hahb-4 protein is involved in plant's response to an environment stress, such as, water stress (drought), by binding to a dehydration transcription regulating region of a stress inducible plant promoter present within plant genome. The reference further discloses a cDNA clone (same as vector) comprising a promoter operably linked to the cDNA sequence encoding the Hahb-4 protein disclosed in the reference.

See in particular, page 633, abstract; pages 633-634, materials and methods; page 635, figure 1; page 637, figure 2; page 638, figures 3-6; page 639, paragraph bridging the left and right columns.

Accordingly, Gago anticipated the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 9-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gago et al. (Plant, Cell and Environment, 25:633-640, Published May 1, 2002) and further in view of Bidney et al. (US Patent No. 6,265,638, Issued July 24, 2001).

The claims are broadly drawn to a vector comprising a promoter operably linked to the nucleic acid sequence of SEQ ID NO: 1, SEQ ID NO: 2 or fragments thereof, or wherein the vector drives the expression of the transcription factor Hahb-4 or a functionally active fragment or variant thereof, wherein said transcription factor Hahb-4 or a functionally active fragment or variant thereof is capable of binding to a dehydration transcription regulating region of plant species, or wherein the expression of the vector in a host cell provides an increased tolerance to environmental stress as compared to a wild type variety of such host cell or a transgenic plant stably transformed with a nucleic acid molecule having a sequence selected from the group comprising SEQ ID NO: 1, SEQ ID N 2 and fragments thereof, wherein the nucleic acid molecule encodes the transcription factor Hahb-4 or a functionally active fragment or variant thereof, or wherein the expression of the nucleic acid in the plant provides increased tolerance to environmental stress, or wherein environmental stress is drought, salinity, osmotic or cold stress, or wherein the plant is water stress tolerant by binding the transcription

factor Hahb-4 or a functionally active fragment or variant thereof to a dehydration transcription regulating region of the plant, or a plant seed or host cell transformed with a nucleic acid molecule having a sequence of SEQ ID NO: 1, SEQ ID NO: 2 or fragments thereof, wherein the nucleic acid molecule encodes the transcription factor Hahb-4 or a functionally active fragment or variant thereof, or wherein said host cell is a bacterial, insect, plant, animal cell or a plant cell, or a method of producing a water stress tolerant transgenic plant comprising SEQ ID NO: 1, SEQ ID NO: 2, and fragments thereof.

Gago et al. teach a nucleic acid molecule isolated from *Helianthus annuus*, comprising a nucleotide sequence encoding a homeodomain-leucine zipper transcription factor Hahb-4. The reference also teaches that said nucleic acid molecule is a genomic DNA molecule or cDNA molecule. The genomic version of the nucleotide sequence taught in the reference has 100% sequence identity to instant SEQ ID NO: 1, and the cDNA version of the sequence taught in the reference has 100% sequence identity to instant SEQ ID NO: 2. The reference also teaches the protein sequence of Hahb-4 protein which has 100% sequence identity to the protein (Hahb-4) encoded by instant SEQ ID NO: 1 or SEQ ID NO: 2. The reference also teaches that said Hahb-4 protein binds to a 5' -CAAT(A/T)ATG- 3' DNA sequence. The reference also teaches that the Hahb-4 protein is involved in plant's response to water stress (drought, an environmental stress), by binding to a dehydration transcription regulating region of a stress inducible plant promoter. The reference further teaches a cDNA clone (same as vector) comprising a promoter operably linked to the cDNA sequence encoding the

Hahb-4 protein taught in the reference. See in particular, page 633, abstract; pages 633-634, materials and methods; page 635, figure 1; page 637, figure 2; page 638, figures 3-6; page 639, paragraph bridging the left and right columns.

The reference also teaches that Hahb-4 functions in signal cascades that controls ABA-mediated responses of a plant (sunflower) to water stress (see abstract). The reference further teaches that Hahb-4 protein is induced under water stress conditions (see pg 637, figure 2; pg 638, figures 3-6). Gago et al. teachings are also discussed in previous rejection for claims 1-7.

Gago et al. do not teach a method of making a transgenic plant cell or plant.

Bidney et al. teach a method of transforming of plant cells and regeneration of transgenic plant using *Agrobacterium* harboring a plant transformation vector. The reference further teaches that said plant transformation vector comprises a promoter operably linked with a nucleotide sequence of interest. The reference also teaches regenerated, fertile transgenic plants, transgenic seeds produced therefrom, and T1 and subsequent generations. The reference also teaches making a monocot (e.g. maize) or dicot (e.g. sunflower) transgenic plant using said method. The reference also teaches stable integration of a transgene (a foreign gene of interest) into the genome of transgenic plant using said method. See in particular, claims 1-23; examples 1-7; tables 1-2.

At the time the invention was made, it would have been prima facie obvious to one of ordinary skill in the art to transform any plant species with a nucleic acid sequence encoding Gago et al. Hahb-4 protein using any method of plant

transformation including the one taught by Bidney et al. to obtain a transgenic plant (monocot or dicot) overexpressing Hahb-4 protein.

Given that Gago et al. clearly teach that Hahb-4 protein is induced (over-expressed) in a plant (sunflower) in response to drought or water stress, and Hahb-4 protein regulates the expression of drought inducible promoter(s) through its binding with the dehydration responsive elements present within said promoter, one of ordinary skill in the art would have been motivated to overexpress a nucleic acid sequence encoding Gago et al. Hahb-4 protein in any plant (monocot or dicot) for the purpose of obtaining a water stress (drought) tolerant transgenic plant with reasonable expectation of success.

Obviously seeds would have also been produced for the purpose of propagation and sale of said water stress (drought) tolerant transgenic plants.

Thus, the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

Conclusions

12. Claims 1-21 are rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)272-0975. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vinod Kumar 2-13-2008

Vinod Kumar
Examiner, Art Unit 1638